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| 10/565,346 | 01/20/2006 | Jane Hirsh | CP115 | 1923 |

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EXAMINER

HAGHIGHATIAN, MINA

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| ART UNIT | PAPER NUMBER |
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1616

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10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/565,346 | Applicant(s) HIRSH ET AL. | |
| | Examiner Mina Haghighatian | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the preliminary Amendments filed on 05/24/07. Claim 2 has been cancelled and claims 3, 6 and 9 have been amended to correct dependency. Accordingly, claims **1 and 3-13** are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "predominantly" in claim **12** is a relative term which renders the claim indefinite. The term "predominantly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 13 is rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Tamarkin et al (US 20060140984).

Tamarkin et al disclose an alcohol-free cosmetic or pharmaceutical foam carrier comprising water, a hydrophobic solvent, a foam adjuvant agent, a surface-active agent and a water gelling agent (see abstract). The said alcohol-free foamable carriers, when placed in an aerosol container and combined with a liquefied gas propellant, create an oil in water emulsion, which upon release from the aerosol container, provides a therapeutically beneficial foam product (see [0025]). The foam carrier includes active agents, both water soluble and oil soluble (see [0063]). The foam is easily spreadable, allowing treatment of large areas as the arms, back, legs and breast (see [0064]). Examples of suitable propellants include volatile hydrocarbons such as butane and fluorocarbon gases (see [0115]). Examples of suitable active agents include antibiotics, antifungals, anesthetics, anti-inflammatory agents, corticosteroids, etc (see [0226]). Anti-inflammatory agents include clobetasone, betamethasone, diclofenac, ketorolac, ibuprofen (see [0245] and [0252]-[0257]). Antifungals include fluconazole, ketoconazole, clotrimazole, etc (see [0234] to [0237]). Antibiotics include penicillins, macrolides, beta-lactams, etc ([0229]). Anesthetics include lidocaine, bupivacaine, dibucaine, etc (see [0264]). Example 8 discloses a foam formulation comprising antibacterials in an amount of about 2%. Example 9 discloses a foam formulation comprising 1-2% antifungals. Example 10 discloses foam formulations comprising 0.05 to 1% of corticosteroid anti-

inflammatory agents. Example 18 discloses a foam formulation comprising 4% lidocaine. Example 1 discloses a method of preparing the foam formulations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060233721).

Tamarkin et al teach foamable composition for administration to the skin, body surface, body cavity or mucosal surface, e.g. the mucosa of the nose, mouth, eye, ear, respiratory system, etc. The foamable oil in water emulsion composition includes: an oil globule system, selected from the group consisting of oil bodies; and sub-micron oil globules, about 0.1% to about 5% by weight of an agent, selected from the group

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consisting of a surface-active agent, having an HLB value between 9 and 16 and a polymeric agent and a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the total composition, water and optional ingredients are added to complete the total mass of 100% (see abstract and [0012]).

The said foamable composition further includes at least one therapeutic agent such as an anti-inflammatory agent, antifungal or antibacterial, anesthetics etc (see [0026]). A polar solvent such as polyols ([0064]). The foamable compositions may be substantially alcohol-free, i.e. free of short chain alcohols, having up to 5 carbon atoms in their carbon chain skeleton (see [0066]). The formulations may be in an oil-in-water emulsion ([0080]). Suitable propellants include volatile hydrocarbons and fluorocarbon gases ([0098]). Claim 1 is drawn to a foamable oil in water emulsion composition comprising an oil globule, a non-ionic surface active agent, water and a liquefied propellant.

Tamarkin et al does not anticipate the claims because they do not exemplify an alcohol-free aerosol foam in an emulsion form consisting of active agents and propellants, however they disclose sufficient information to one of ordinary skill in the art to make and use the invention as claimed. In other words, the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Claims 1, 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 17-19 of copending Application No. 11/128,947 (US 20050255048). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the foam composition comprising an antifungal or antibacterial active agents and propellant of the reference claims and the spray or foam formulations comprising one or more antifungal or antibacterial active agents of the instant claims are essentially the same or very similar in scope. One of ordinary skill in the art would have been able to make the simple modifications with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 9-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-16 of copending Application No. 11/464,100 (US 20070036731). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the topical composition comprising a particulate material, wherein the particulate material comprises an antibiotic or an antifungal agent, and a propellant of the reference claims and the spray or foam formulations comprising one or more antifungal or antibacterial active agents of the instant claims are very similar in scope. One of ordinary skill in the

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art would have been able to make the simple modifications with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1 and 3-13** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-16 of copending Application No. 11/552,457 (US 20070154402). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the topical composition comprising one or more keratolytic agents in an oil-in-water emulsion and a propellant and one or more active agent such as an antibiotic, an antifungal agent, an anti-inflammatory agents, anesthetics, etc, of the reference claims and the aerosol foam formulations in an oil-in-water emulsion comprising one or more antifungal, antibacterial, anti-inflammatory or anesthetic agents of the instant claims are very similar in scope. One of ordinary skill in the art would have been able to make the simple modifications with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mina Haghighatian
Patent Examiner
September 30, 2007